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| 10/029,345 | 12/20/2001 | Donald G. Jackson | D0072 NP | 5523 |

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| EXAMINER | |
|---|---|
| SWOPE, SHERIDAN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1652 | |

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/029,345 | JACKSON ET AL. | |
| | Examiner | Art Unit | |
| | Sheridan L. Swope | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *June 18, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *26-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *27,29,30 and 35* is/are allowed.

6)☒ Claim(s) *26,31-34,36-44,48-50 and 56* is/are rejected.

7)☒ Claim(s) *28,32 and 44-55* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1102*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's election, without traverse, of Invention I, Claims 1-4, 8, 9, 16-19 and SEQ ID NOs: 108 and 109, in their response of June 18, 2004, is acknowledged. Applicant's cancellation of Claims 1-25 and addition of New Claims 26-56 is acknowledged. New Claims 26-56 are deemed to be encompassed by the elected invention and are hereby examined.

### *Priority*

The Examiner notes the following regarding the provisional applications recited as priority documents. Neither application 60/256,868 nor application 60/280, 186 disclose the sequences of SEQ ID NO: 108 or SEQ ID NO: 109. The sequences of SEQ ID NO: 108 and 109, as well as the mutations of residues 180, 193, 284, and 293 recited in the instant application, are disclosed in applications 60/287,735, 60/295,848, and 60/300,465.

### *Specification-Objections*

The specification is objected to for failing to disclose specific SEQ ID Nos being recited and the ATCC deposit numbers and dates of deposit for specific clones. See, for example, page 7, line 20 to page 8, line 19, page 188, lines 27-28, page 189, line 50 to page 190, line 6, and Table 1. All proper SEQ ID Nos, ATCC numbers, and dates of deposit should be inserted into the specification. Correction is required.

The specification is objected to for improper formatting and/or fonts, for example, on page 432-433. The specification should be carefully checked for formatting. Correction is required.

The specification is objected to for having blank areas, for example, on page 455. The specification should be carefully checked for blank spaces. Correction is required.

***Claims-Objections***

The claim set is objected to for inconsistency in the presentation of the word "claim". In some claims said word is presented as "claim" e.g. Claim 27, while in other claims the word is presented as "Claim" e.g. Claim 49. Correction is requested.

Claims 28 and 32 are objected to for the phrase "comprises of nucleotides" on line 2, which should be corrected to "comprises nucleotides".

Claim 39, in reciting "vector sequences of claim 38" is indefinite as, Claim 38 recites an individual vector sequence. It is suggested that Claim 39 be amended to recite "vector sequence of claim 38" or, more concisely, "vector of claim 38". Claim 40, as dependent on Claim 39, is rejected for the same reason.

Claims 44-47 are objected to for reciting non-elected subject matter; polynucleotides comprising the cDNA clone contained in plasmid BMY_HHP5, as set forth by SEQ ID NO: 41 (Table I). Correction is required.

Claim 48 is objected to for improper Markush language. When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation, then "wherein R is A, B, C or D" shall also be considered proper. (M.P.E.P. 2173.05) Correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 48-50 and 56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-14 of US Application 10/648,593, which has the same owner as the instant application (M.P.E.P. 804). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 48-50 and 56 herein and Claims 1-14 of US Application 10/648,593 are both directed to a polynucleotide encoding the polypeptide set forth by SEQ ID NO: 109 herein, wherein said polypeptide has a methionine residue at position 180 and a asparagine residue at position 193. Said polynucleotide and polypeptide are set forth by SEQ ID NO: 123 and 247, respectively, of 10/648,593. The claims differ in that Claims 1-14 of US Application 10/648,593 also recite a plurality of polynucleotides comprising the specified as well as additional polynucleotides, while Claims 48-50 and 56 herein also recite polynucleotides encoding additional variants of SEQ ID NO: 109. The portion of the specification in 10/648,593 that supports the recited polynucleotide, Table 2

and Claim 3, includes embodiments that would anticipate Claims 48-50 and 56 herein, e.g., a polynucleotide encoding the polypeptide set forth by SEQ ID NO: 109 herein, wherein said polypeptide has a methionine residue at position 180 and a asparagine residue at position 193, which is also the polynucleotide specifically recited in Claims 1-14 of US Application 10/648,593. Claims 48-50 and 56 herein cannot be considered patentably distinct over Claims 1-14 of US Application 10/648,593 when there are specifically recited embodiments (polynucleotides encoding the protein set forth by SEQ ID NO: 247 of 10/648,593) that would anticipate Claims 48-50 and 56 herein. Alternatively, Claims 48-50 and 56 herein cannot be considered patentably distinct over Claims 1-14 of US Application 10/648,593 when there are specifically disclosed embodiments in 10/648,593 that supports Claims 1-14 of that application and falls within the scope of Claims 48-50 and 56 herein, because it would have been obvious to a skilled artisan to modify the plurality of polynucleotides of Claims 1-14 of US Application 10/648,593 by selecting a specifically disclosed embodiment that supports those claims, i.e., polynucleotides encoding the protein of SEQ ID NO: 247, as disclosed in 10/648,593 and specifically recited in Claim 3. One having ordinary skill in the art would have been motivated to do this, because such an embodiment, said polynucleotides, is disclosed as being a preferred embodiment within Table 2 and Claim 3 of 10/648,593.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112-Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, 39, 40 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56 is indefinite in reciting "conservative substitutions" which is not defined in the specification. Although very common in the art, the term "conservative substitution" is vague and indefinite. For example, is a Gln/Glu substitution or an Asp/Asn substitution conservative? Are Ser/Tyr and Phe/Tyr conservative substitutions? Another situation that is indefinate is the classification of Gly and Ala; are these small polar residues, similar to Ser, Thr, Gln and Asn, or hydrophobic? Is His basic or hydrophobic? Are linear hydrophobic amino acids similar to aromatic hydrophobic amino acids? Is Cys a small polar amino acid or its own category? Is Tyr a polar amino acid or an aromatic amino acid? Lack of consensus on the answers to these questions causes the term "conservative substitution" to be indefinite.

***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***Enablement***

In this regard, the application disclosure and claims are compared per the factors indicated in the decision re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of

the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; and (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 48-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding the polypeptide of SEQ ID NO: 109, does not reasonably provide enablement for any polynucleotide encoding residues 2-665 of SEQ ID NO: 109 wherein one or more residues of 180, 193, 284, 293, 302, 315, or 584 are substituted with any amino acid or any polynucleotide encoding a mutant of the RET31 polypeptide wherein the mutant retains binding for substrate but the ability to dephosphorylate the substrate is reduced. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 48-55 are so broad as to encompass any polynucleotide encoding residues 2-665 of SEQ ID NO: 109 wherein one or more residues of 180, 193, 284, 293, 302, 315, or 584 are substituted with any amino acid. Claim 56 is so broad as to encompass any polynucleotide that encodes a mutant of the RET31 polypeptide (residues 2-665 of SEQ ID NO: 109), wherein the mutant comprises at least one amino acid substitution within residues 158 to 297, with at least one substitution being a conservative substitution, and wherein the mutant retains binding for substrate but the ability to dephosphorylate the substrate is reduced. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. Since the amino

acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired function, including substrate binding with reduced phosphatase activity, requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of SEQ ID NO: 109 and the nucleotide sequence of SEQ ID NO: 108.

While recombinant and mutagenesis techniques as well as binding and phosphatase assays are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable.

The specification does not support the broad scope of Claims 48-55 which encompasses any polynucleotide encoding residues 2-665 of SEQ ID NO: 109 wherein one or more residues of 180, 193, 284, 293, 302, 315, or 584 are substituted with any amino acid. The specification does not support the broad scope of Claim 56, which encompasses any polynucleotide that encodes a mutant of the RET31 polypeptide (residues 2-665 of SEQ ID NO: 109), wherein the mutant comprises at least one amino acid substitution within residues 158 to 297, with at least one substitution being a conservative substitution, and wherein the mutant retains binding for substrate but the ability to dephosphorylate the substrate is reduced. The specification does not

support the broad scope of Claims 48-56 because the specification does not establish: (A) which polynucleotides encode variants of 2-665 of SEQ ID NO: 109, wherein one or more residues of 180, 193, 284, 293, 302, 315, or 584 are substituted with any amino acid, have phosphatase activity; (B) which amino acids can be substituted at positions 180, 193, 284, 293, 302, 315, or 584 and still retain the desired activity; (C) regions of the protein structure, within residues 158-297 of SEQ ID NO: 109, which may be modified without effecting the substrate binding activity of the RET31 polypeptide; (D) the general tolerance of the substrate binding activity of the RET31 polypeptide to modification and extent of such tolerance; (E) regions of the protein structure, within residues 158-297 of SEQ ID NO: 109, which may be modified to reduce the phosphatase activity of the RET31 polypeptide; (F) the general tolerance of the phosphatase activity of the RET31 polypeptide to modification and extent of such tolerance; (G) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (H) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of polynucleotides encoding residues 2-665 of SEQ ID NO: 109 wherein one or more residues of 180, 193, 284, 293, 302, 315, or 584 are substituted with any amino acid or any number of polynucleotides encoding any mutant of the RET31 polypeptide (residues 2-665 of SEQ ID NO: 109), wherein the mutant comprises at least one amino acid substitution within residues 158 to 297, with at least one substitution being a conservative substitution, and wherein the mutant retains binding for substrate but the ability to

dephosphorylate the substrate is reduced. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim 44 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention employs a novel plasmid encoding RET31 deposited with ATCC as No. PTA-3434. Since the plasmid is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmid's sequences are not fully disclosed nor have they been shown to be readily available to the public. The specification does not disclose a repeatable process to obtain the vectors and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of these plasmids should have been made in accordance with 37 CFR 1.801-1.809.

If the deposit is/was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit is not/has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request;

2. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

4. the deposit will be replaced if it should ever become inviable.

***Written Description***

Claims 48-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of DNA molecules either encoding any polypeptide comprising residues 2-665 of SEQ ID NO: 109 wherein one or more residues of 180, 193, 284, 293, 302, 315, or 584 are substituted with any amino acid, wherein the polypeptide has phosphatase activity (Claims 48-55) or a genus of polynucleotides that encodes a mutant of the RET31 polypeptide (residues 2-665 of SEQ ID NO: 109), wherein the mutant comprises at least one amino acid substitution within residues 158 to 297, with at least one substitution being a

conservative substitution, and wherein the mutant retains binding for substrate but the ability to dephosphorylate the substrate is reduced (Claim 56). The specification teaches the structure of no representative species of such DNAs. Moreover, the specification fails to describe any representative species by any identifying characteristics or properties other than the functionality of encoding either a polypeptide comprising residues 2-665 of SEQ ID NO: 109 wherein one or more residues of 180, 193, 284, 293, 302, 315, or 584 are substituted with any amino acid, wherein the polypeptide has phosphatase activity (Claims 48-55) or a mutant of the RET31 polypeptide (residues 2-665 of SEQ ID NO: 109), wherein the mutant comprises at least one amino acid substitution within residues 158 to 297, with at least one substitution being a conservative substitution, and wherein the mutant retains binding for substrate but the ability to dephosphorylate the substrate is reduced (Claim 56). Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 48-50 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagase et al, 2000 (IDS). Nagase et al, 2000 teach a polynucleotide encoding a polypeptide having 99.6% identity with SEQ ID NO: 109, wherein, at positions corresponding to residues 180 and 193 of SEQ ID NO: 109, said polypeptide has a methionine and an asparagine, respectively.

Claims 48-50 and 56 are rejected under 35 U.S.C. 102(a) as being anticipated by Nagase et al, 2001. Nagase et al, 2001 teach a polynucleotide encoding a polypeptide having 99.6% identity with SEQ ID NO: 109, wherein, at positions corresponding to residues 180 and 193 of SEQ ID NO: 109, said polypeptide has a methionine and an asparagine, respectively.

Claims 48-50 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Meyers et al, 2003; priority date of March, 24, 2000. Meyers et al teach a polynucleotide encoding a polypeptide having 99.6% identity with SEQ ID NO: 109, wherein, at positions corresponding to residues 180 and 193 of SEQ ID NO: 109, said polypeptide has a methionine and an asparagine, respectively.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.

REBECCA E. PRUTY
PRIMARY EXAMINER
GROUP ~~1800~~
1600